CENTER FOR BIOLOGICS EVALUATION AND RESEARCH
FOOD AND DRUG ADMINISTRATION
DEVICE ACTION PLAN
FINAL REPORT

On April 26, 1999, the Device Action Plan (attachment 1) was initiated by the Center for Biologics Evaluation and Research, agreed upon and signed by the Center for Biologics Evaluation and Research, the Center for Devices and Radiological Health, the Associate Commissioner for Regulatory Affairs and the Commissioner of Food and Drugs.

The Device Action Plan was developed in order to facilitate the implementation of the device provisions of the FDA Modernization Act of 1997 and to assure consistency of policy and procedures. The plan addressed areas of cooperation, coordination and communication to assure harmonized activities. It focused on review practices and performance goals under the Managed Review Process and included outreach activities to maintain input and feedback from industry and the public.

Over the past year, the staffs from CBER, CDRH, and ORA have worked together to harmonize and improve the application process for devices. The staffs improved policy, procedures, and outreach activities, which provides the underpinning for a solid review process, and is dedicated to continue this standard as we enter the new millennium. The Device Action Plan team has completed the tasks as defined in the April 26, 1999 Device Action Plan (attachment 2). The team provided six-month reports on October 29, 1999 (attachment 3), and again on April 26, 2000 (attachment 4). A Device Management Team has been created to oversee device activities at CBER (attachment 5). It is agreed that the intent of the April 26, 1999 Device Action Plan has been fulfilled.

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DATE: July 20, 2000

5 Attachments
1. DAP, 4/26/99
2. DAP Completions, 4/26/00
3. DAP Six-Month Report, 10/29/99
4. DAP Six-Month Report, 4/26/00
5. Device Management Team